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CS

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/578,669	05/25/00	GRABSTEIN K	2831-E

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HM12/0906

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EXAMINER

NAVARRO, A

ART UNIT	PAPER NUMBER
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1645

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DATE MAILED: 09/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/578,669

Applicant(s)
Grabstein et al

Examiner
Mark Navarro

Art Unit
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 20, and 23-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1, 2, 20, and 23-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, and 20 drawn to antagonists which are muteins of IL-15, classified in class 530, subclass 350.
 - II. Claim 1-2, and 20 drawn to antagonists which are monoclonal antibodies, classified in class 530, subclass 388.1.
 - III. Claims 1-2, 20 and 23, drawn to antagonists which are conjugated IL-15 molecules, classified in class 530, subclass 345.
 - IV. Claims 24-25, drawn to methods of treatment with antagonists which are muteins of IL-15, classified in class 424, subclass 184.1.
 - V. Claims 24-25, drawn to methods of treatment with antagonists which are monoclonal antibodies, classified in class 424, subclass 141.1.
 - VI. Claims 24-25, drawn to methods of treatment with antagonists which are conjugated IL-15 molecules, classified in class 514, subclass 2.
 2. The inventions are distinct, each from the other because of the following reasons:

Invention I, drawn to a mutein of IL-15, is distinct from Inventions II-VI, since the mutein of IL-15 requires altering the primary amino acid sequence of the IL-15 molecule. Furthermore,
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the antibody of Invention II, will display an inherent affinity, avidity, and specificity for a given epitope, that muteins or conjugated molecules will not display.

Invention III, drawn to conjugated IL-15 molecules, is distinct from Inventions I-II, and IV-VI, since it requires the additional step of conjugating an inert moiety selected from the group consisting of PEG, mPEG, PVP and dextran, to the IL-15 molecule.

Inventions IV-VI and I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the mutein, monoclonal antibody, and conjugated IL-15 molecule can be used in vivo to inhibit IL-15 activity, or alternatively may be incorporated into an in vitro assay to detect the IL-15 receptor.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.



Mark Navarro

Primary Examiner

September 5, 2001
